

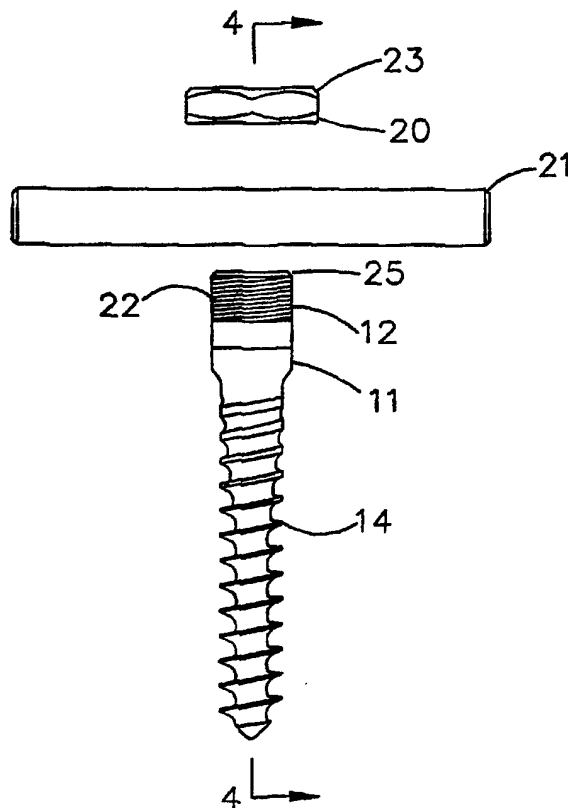


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(21) International Application Number: PCT/US94/13318 (22) International Filing Date: 17 November 1994 (17.11.94) (30) Priority Data: 08/154,987 19 November 1993 (19.11.93) US (71) Applicant: CROSS MEDICAL PRODUCTS, INC. [US/US]; 4168 Fisher Road, Columbus, OH 43228-1024 (US). (72) Inventors: MELLINGER, Philip, A.; 1094 Kirk Avenue, Worthington, OH 43085 (US). BYRD, J., Abbott, III; 3767 Oyster Point Qway, Virginia Beach, VA 23452 (US). PUNO, Rolando, M.; 11819 Lake Stone Way, Prospect, KY 40059 (US). THEKEN, Randall, R.; 1115 Robinson Avenue, Barberton, OH 44203 (US). (74) Agents: SHUNK, Laura, F. et al.; Hudak & Shunk Co., L.P.A., Suite 808, 156 South Main Street, Akron, OH 44308-1304 (US).		(81) Designated States: AU, BR, CA, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: SPINE ROD ANCHORS, SPINE ROD CONNECTORS AND NUT ALIGNMENT GUIDE**(57) Abstract**

This invention is a spine rod anchor (11) having a channel (17) for receiving a spine rod (21), and having a nut or set screw for retaining the spine rod (21) in the channel; a parallel connector (100) for connecting a pair of parallel spine rods, the parallel connector (100) having a pair of parallel rod receiving channels (107) and set screws for retaining a respective spine rod therein; an axial connector (70) for connecting axially aligned spine rods, the axial connector (70) having a pair of axially aligned rod receiving channels (78) and set screws for retaining a respective spine rod therein; and a nut alignment guide (210) for alignment and engagement of a nut (23).



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SPINE ROD ANCHORS, SPINE ROD CONNECTORS AND NUT ALIGNMENT GUIDE

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FIELD OF INVENTION

This invention relates to orthopedic implants, and more particularly to a bone interface anchor or connector for securely holding a stabilization rod. The anchor or connector has means to inhibit movement of the rod after it is locked into position. Further, an instrument is provided for applying a nut to the anchor to compressively add the rod.

10

BACKGROUND

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As surgical techniques have advanced, it has become increasingly common for surgeons to use specially designed hardware for the internal fixation of bones. A particular area of concentration for the recent development of this technology has been the spine. Internal fixation is used most frequently in the spine in conjunction with vertebral fusion, and also for the manipulation of the spine to correct spinal deformities such as scoliosis.

20

There are several important criteria for a hardware system which is used internally for spinal fixation:

25

1. The implant should provide rigidity as is indicated, generally along the long axis of the patient's spine.

30

2. The system should be able to accommodate a broad variation in the size and shape of the spinal member with which it is used. For example, the surgeon may wish to use the implant on a variety of individuals. In addition, the difference in the area and size of the point of fixation is compounded by the change in the shape of the vertebrae over the length of the full spinal column. Since it is an advantage to allow the surgeon to master implanting a particular type of assembly, it is preferable if the same or similar anchoring means can be used for a

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variety of locations. This advantage results in cost efficiency of inventory as well as efficiencies with respect to minimizing the operating time.

5 3. The hardware must be able to apply and oppose considerable stresses and strains. Thus, the anchor means must be securely fixed to the bone, and the stabilizer must be securely fixed with regard to the anchor means. Moreover, it is desirable to provide the hardware with the integrity to resist breaking.

10 4. The system should be designed for ease of implantation and removal. Implant hardware is relatively small and therefore somewhat difficult to manipulate. Any difficulty with assembly is compounded by the fact that the assembly occurs during surgery and in a living being.
15 Therefore, it is critical that the hardware is designed with the surgeon's convenience in mind, i.e., to limit the time required and the stress required to implant an assembly. Consequently, a fixation system should be designed to the extent possible for easy assembly while
20 maintaining the option of removal where necessary.

SUMMARY OF THE INVENTION

 The present invention relates to an implant anchor or connector seat used with the spinal implant
25 systems previously described and in particular used with a spinal implant system having an elongated rod stabilizer and a plurality of rod holding members. These holding members are anchored to the bone or connector rods in relation to each other. In particular, this invention
30 provides a rod seat used in a rod connector or anchor member having interrupted serrations. The rod seat has a rod receiving channel which receives the rod about its longitudinal axis. Each rod receiving channel includes at least one, and preferably a plurality of serrations, the
35 serrations extending in the direction of the longitudinal axis of the rod. This serration or serrations include an interruption such as a transverse channel, which forms a

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transverse edge in the serration or serrations. The serrations inhibit the rod from rotational movement, i.e., from rotation about the longitudinal axis of the rod. The transverse edge inhibits the rod from longitudinal movement, i.e., along the longitudinal axis of the rod. It is thus an object of the invention to provide a rod seat means having serrations and a transverse channel to inhibit rotational and axial movement of the rod. It is a further object of the present invention to provide for means to inhibit against rotational and axial movement of the rod which means has a limited possibility of wear debris which could contaminate the wound. It is a further object of the invention to provide means to inhibit rod movement which means are relatively easy to manufacture.

It is a further object of the invention to provide a rod holder or connector which has improved compressive grip on a spinal stabilization rod. It is another aspect of the invention to provide a novel closed rod anchor means which consists essentially of a rod seat means and a set screw and which achieves sufficient compressive force on the rod for stabilization of a spine. It is a further object of the invention to provide a novel connector to connect two spinal stabilization rods which connector consists essentially of a connector body and two set screws for axial connection of rods in one embodiment and parallel connection of the rods in a second embodiment.

As the second embodiment of the invention utilizes a means to achieve compression on the rod which is a two-component clamp, having mating threads, it is a further object of the invention to provide means to align the compression means so as to inhibit cross-threading of the clamp threads. Thus, in accordance with this embodiment of the invention, the chances of cross-threading the nut onto the anchor are reduced. Therefore, it is another object of the present invention to provide an instrument which inhibits cross-threading of the compression means

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relative to the stabilizer anchor. It is both frustrating to the surgeon and threatening to the health of the patient if the retaining means is cross-threaded relative to the seat member during the course of the operation. The present invention acts to axially and laterally align the retaining means relative to the seat in order to inhibit cross-threading.

It is an object of the present invention to provide an instrument for use in implantation of a bone fixation device which will simultaneously hold and align a compression means, such as a cap or bolt relative to the seat means, and further to allow a cooperative union between the seat means and the compression means so as to apply a compressive force to the rod means.

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BRIEF DESCRIPTION OF DRAWINGS

Figure 1 is an exploded side view of an implant assembly in accordance with the first embodiment of the invention;

Figure 2 is an exploded front view of the assembly shown in Figure 1;

Figure 3 is a cross-section of the implant assembly as shown in Figure 1 taken along line 3-3 in Figure 2;

Figure 4 is a cross-section of the implant assembly shown in Figure 1 taken along line 4-4 in Figure 1;

Figure 5 is a top plan view of the unified anchor seat and screw as shown in Figure 1;

Figure 6 is a cross-section of the unified anchor seat and screw as shown in Figure 4;

Figure 7 is an exploded side view of a second embodiment of the spinal implant assembly in accordance with the present invention;

Figure 8 is an exploded front view of the anchor assembly of the embodiment of the anchor assembly shown in Figure 7;

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Figure 9 is a cross-section of the second embodiment of the implant assembly shown in Figure 7 taken along line 9-9 of Figure 8;

5 Figure 10 is a cross-section of the implant assembly shown in Figure 7 taken along line 10-10;

Figure 11 is a top plan view of an axial rod connector in accordance with the third embodiment of the invention;

10 Figure 12 is a cross-sectional view of the axial rod connector as shown in Figure 11 taken along line 12-12;

Figure 13 is a top plan view of the axial rod connector shown in Figure 11;

15 Figure 14 is a front plan view of a parallel rod connector in accordance with the fourth embodiment of the invention;

Figure 15 is a top plan view of the parallel rod connector in accordance with the parallel rod connector in Figure 14;

20 Figure 16 is a cross-sectional view of the parallel rod connector taken along line 16-16 of Figure 15;

25 Figure 17 is a side view of a nut alignment guide for use in implanting the assembly shown in Figure 5;

Figure 18 is a side view of the nut alignment guide shown in Figure 17 and rotated 90° with respect thereto;

30 Figure 19 is an end view of the alignment guide shown in Figures 17 and 18;

Figure 20 is a cross-section of the barrel of the nut alignment guide;

Figure 21 is an end view of the nut receiving end of the barrel;

35 Figure 22 is a top view of the torque end of the barrel shown in Figure 20, and

Figure 23 is a side view of the shaft of the nut

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guide alignment instrument shown in Figure 17.

DETAILED DESCRIPTION OF THE INVENTION

5 A spinal implant assembly in accordance with the present invention is illustrated in Figure 1. The implant assembly comprises a rod anchor 11, a rod 21, and compression means 23. In the first embodiment, the anchor 11 includes seat means 12 and fixation means 14 which is a screw. It should be understood, of course, that the anchor could include alternative fixation means such as a vertebral hook. Likewise, the rod 21 could be replaced by other elongated stabilization means such as a slotted plate. The rod 21 is held in relation to the anchor 11 by a compression member which is illustrated as a nut 23 having internal threads 26 which mate with external threads 22 on the seat means 11 to bias the rod into an engagement with a rod channel in the seat means. Again, alternative compression means could be used for the present invention such as a set screw member as is illustrated in the second embodiment of the present invention.

20 The seat 12 has a necked portion 16 which tapers to the screw 14 and provides for a bone interface area. The seat 12 further includes a channel 17 which passes through the seat 12 in a first direction and which receives the rod 21 along its longitudinal axis.

25 In accordance with the present invention, the channel 17 includes a contoured rod contacting surface and more preferably includes one or more serrations to inhibit the movement of the rod 21. It is particularly preferred that the serrations run in the first direction, parallel to the longitudinal axis of the rod in order to inhibit rotation of the rod about its longitudinal axis.

30 In addition, as is illustrated in Figure 5, the serrations include a central cross-channel portion 29, which interrupts the serrations and forms lateral edges 30, which are substantially perpendicular to the longitudinal axis of the rod. These edges abut with the serrations.

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tions 28 to form toothed ridges which help to hold the rod against translation along its longitudinal axis.

5 In accordance with the present invention, the rod channel 17 includes one or preferably a plurality of serrations 28 which extend from about 5° to about 180° degrees, more preferably from 60° to 120° about the channel.

10 The serrations have a depth of about 0.005 to about 0.020 inch, and preferably about 0.010 to about 0.015 inch and have a crest to crest spacing of from about 0.010 to about 0.040 inch, and preferably about 0.020 to about 0.030 inch. As used herein, an interruption means a contour in the serrations. In addition, the serrations include an interruption or cross-channel 29 which provides
15 lateral edge areas 60 which hold the rod 21 against translational along its longitudinal axis. The channel is at least as deep as the trough of the serrations and preferably is between about 1.5 to about 2 times as deep. The channel has a width from 1/4 to 2/3 of the width of
20 the rod receiving channel with the remaining width being taken by serrations; preferably, the channel is about 3/16 inch wide for most screw sizes.

The nut 23 includes ridges on its face which contacts the rod 21 in order to improve the compressive
25 contact between the nut 23 and the rod 21 as well as to protect the mating interface between the threads 22 and the threads 26 of the nut.

In addition, the nut 23 has a chamfered area 24 on its top side in order to avoid rough edges which
30 interface with the muscle. The seat member 12 includes a top bevel 25 to facilitate threading of the nut 23 on the threads 22. Further, the anchor 11 includes countersunk areas 19 which helps to maintain the anchor 11 in an instrument when the anchor is implanted, and which further
35 serves to help align the nut holder, so as to inhibit cross-threading of the nut 23 on the seat threads 22.

A second embodiment of the present invention is

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shown in Figures 7-10. This embodiment illustrates a closed anchor member 42. Closed anchor refers to an anchor which at least substantially partially includes the rod so that the anchor means will withstand hoop stresses introduced by manipulating the rod within the anchor. The assembly is shown generally at 40, and comprises anchor member 41 which includes seat means 42 and fixation means 44 which comprise a screw in the present case. Again, it is envisioned that a vertebral hook could be used instead of a screw. The seat 42 includes an upper bevel 43 to eliminate edges which interface with the patient's muscle. In addition, the seat 42 has a rod channel 47 which receives a rod 51. The seat means 42 has a tapered area 46 which forms a bone interface area. The seat means 12 further includes a bore 48, which is substantially perpendicular to the rod receiving channel 47. The bore 48 includes internal threads 52 which mate with the external threads 56 of a set screw member 49. The set screw member 49 has an internal hex 50 which allows the set screw to be screwed into contact with seat 12. In addition, the set screw 49 advantageously includes a beveled portion 54 which interfaces with the rod 51. The bevel advantageously includes toothed area 54 which increases the compressive grip of the set screw 49 on the rod 51.

A third embodiment of the invention is shown in Figure 11 which comprises an axial rod connector. The axial connector 70 includes connector seat means 72 having an internal bore 76 and including rod receiving channels 77. The bore 76 includes an intermediate necked portion which forms rod abutments 78 which form a positive stop for the end of the rod. In addition, the axial connector includes set screw holes 79 which are advantageously aligned along the longitudinal axis of the rod. In accordance with the invention, the axial connector includes a plurality of serrations 88 which are interrupted as set forth previously herein so as to inhibit both rotational and axial misalignment or movement.

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A fourth embodiment of the invention is shown in Figures 14-16, and comprises a parallel connector 100. The parallel connector includes connector seat means 102 having parallel rod channels 107. The rod channels include substantially perpendicular set screw holes 109 which receive set screws as are previously illustrated which apply a compressive force to a rod, to bias the rod into contact with interrupted serrations 118 as is previously discussed. In addition, the parallel connector includes indentations 103 for a connector holder for ease of insertion.

A fifth embodiment of the invention is shown in Figure 17-22 and relates generally to an alignment guide for use with a anchor system which incorporates a nut. In particular, the alignment guide is shown generally at 217 in Figures 17 and 18. The guide has handle means 214, a head portion 216 which is contoured to mate with an anchor, an elongated central portion 218 which allows the surgeon to access the anchor means through the wound.

More particularly, the guide 210 includes an inner shaft 220 and a concentric rotationally disposed outer barrel 222 having a recess 225 and distal to the handle. The recess 225 is configured to receive a nut. The barrel includes a high friction surface such as knurling 227 to increase the ability of the surgeon to rotate the barrel relative to the shaft in order to initially engage the nut on the anchor seat.

In addition, the barrel includes a hex- shaped end 230. This is adapted for use with an open end extension which fits over the hex on the barrel and allows the barrel to be tightened to a predetermined amount of torque using a deflection beam torque wrench. As is shown in Figures 20-22, the barrel includes a stepped central bore 232. The bore has a narrowed portion 234 which is a slightly larger diameter than the center portion 236 of the inner shaft 220. A shoulder 240 mates with a bevelled area 242 on the shaft head 216 in order to restrain the

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shaft 220 from disengaging the barrel 222.

5 The shaft head 216 includes a increased diameter section 244 which fits through the center bore of the nut so that the nut can be inserted over the shaft head onto the anchor. The shaft head 216 further includes a annular flange 246 which abuts with the top lateral surface of the rod anchor. This flange helps to align the placement of the axis of the nut alignment guide in order to properly align the nut relative to the seat in order to avoid cross-threading. In addition, the head 216 includes a contoured end 250 having rounded opposing hips 252 which mate with indentations in the anchor. The contoured end 250 is otherwise shaped to have an elongate center portion which will mate with the rod receiving channel of the anchor. Thus, the surgeon may extend the barrel over the shaft in the direction of the contoured end in order to place a nut in the nut recess 225. Then the barrel, which is slidably disposed about the longitudinal axis of the shaft may be retracted to expose the contoured end of the nut alignment guide. The contoured end of nut alignment guide may be engaged in the rod receiving channel of the anchor and the barrel may be slid back down the shaft until the shoulder 240 of the guide barrel engages the bevel 242 of the inner shaft. The barrel 220 may be rotated relative to the seat member by using the grip 227 to begin the engagement of the nut on the seat. Subsequently, the open end extension may be fitted on the hex end of the barrel and on the deflection beam torque wrench in order to apply a controlled amount of torque to the nut to cause a compression of the nut on the rod.

While in accordance with the Patent Statutes, the best mode and preferred embodiment has been set forth, the scope of the invention is not limited thereto, but rather by the scope of the attached claims.

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WHAT IS CLAIMED IS:

1. A component of a spinal implant assembly comprising a stabilization rod seat having a rod receiving channel, said channel including a rod mating surface, said rod mating surface being contoured to inhibit said rod against movement along and rotation about the longitudinal axis of the rod.
2. A component of a spinal implant system as set forth in claim 1, wherein said channel receives said rod and has a longitudinal axis extending in the direction of the longitudinal axis of the rod, said channel including at least one ridge extending in the longitudinal direction of said channel.
3. A component as set forth in claim 2, wherein said ridge includes an interruption.
4. A component as set forth in claim 3, wherein said channel includes a plurality of serrations.
5. A component as set forth in claim 4, wherein said serrations extend through an arc of from about 5° to about 180° along said channel in said body.
6. A component as set forth in claim 5, wherein said serrations extend through an arc of from about 60° to about 120° along said channel in said body.
7. A component as set forth in claim 5, wherein said interruption comprises a transverse channel.
8. A rod anchor for a rod used in the stabilization of a spine, said anchor consisting essentially of: anchor means having a rod receiving channel and having unified means to fix said anchor means to a vertebral body, and a compression member which cooperates with said

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anchor means to compressively capture said rod.

5 9. An anchor as set forth in claim 8, wherein said compressive means comprises a threaded locking member.

 10. An anchor as set forth in claim 9, wherein said threaded locking member is a nut.

10 11. An anchor as set forth in claim 8, wherein said rod receiving channel includes a plurality of serrations.

15 12. An anchor to be used with a rod for the stabilization of a spine, comprising anchor means having unified means to fix said anchor to a vertebral body, and including a closed rod receiving channel which captures the rod, said rod receiving channel including means to inhibit said rod from axial and longitudinal displacement
20 and compression means which cooperate with said anchor means to cause top loaded compression on said rod.

 13. An anchor means as set forth in claim 12, wherein said means to inhibit rotational and axial displacement
25 comprise said channel having a contoured rod mating surface.

 14. An anchor means as set forth in claim 13, wherein said contoured rod mating surface comprises a
30 plurality of interrupted serrations.

 15. A connector for use with a spinal implant assembly comprising a stabilization rod and rod receiving anchors,
35 said connector comprising a body having a rod receiving channel which has a rod mating surface with serrations.

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16. A connector according to claim 15, wherein said channel had a longitudinal axis and said serrations are parallel with said longitudinal axis.

5 17. A connector according to claim 16, wherein said serrations are interrupted by a channel transverse to said longitudinal axis.

10 18. An apparatus for the assembly of a medical implant, the implant having a seat member and an elongated stabilizer and stabilizer retaining means which is loaded from the top onto said seat member; the apparatus comprising releasable holding means which releasably holds said stabilizer retaining means in a top position relative to
15 the stabilizer in said seat member whereby said stabilizer retaining means is engaged and rotated relative to said seat member to secure said stabilizer in said seat member and the retaining means is subsequently released from said holding means, and further, wherein said stabilizer retaining means aligns the stabilizer retaining means and
20 the seat members in concentric alignment along its longitudinal axis and aligns a lateral terminus of the stabilizer retaining means and a lateral terminus of the seat member to enable the proper engagement of the stabilizer retaining means and the seat member.
25

19. An apparatus as set forth in claim 18, wherein said stabilizer retaining means is threaded and said seat member is threaded.

30

20. An apparatus as set forth in claim 19, wherein said alignment means is a shaft, said shaft having a contoured head which forms a mating engagement with the seat member and said releasable holding means is a barrel
35 which is journaled about said shaft and which includes a recess having a mating configuration with at least a top portion of said stabilizer retaining means.

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21. An apparatus as set forth in claim 20, wherein said holding means comprises a hexagonal recess and said retaining means comprises a hexagonal shaped nut.

5 22. An apparatus as set forth in claim 21, wherein said contoured alignment means has an annular flange which mates with a top lateral portion of said seat member and said barrel is movable in a longitudinal direction about said shaft.

10 23. An apparatus as set forth in claim 18, wherein said alignment means further includes a means to engage a deflection beam torque wrench in order to permit a defined amount of torque to be applied to said retaining
15 means.

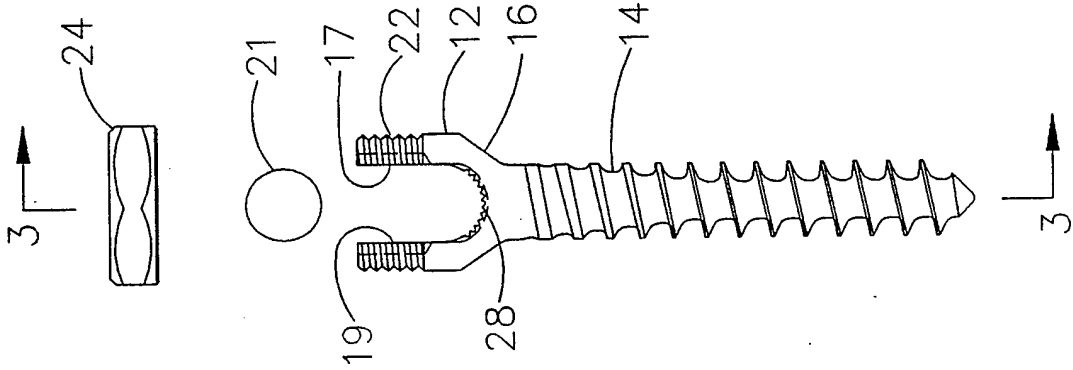


FIG. 2

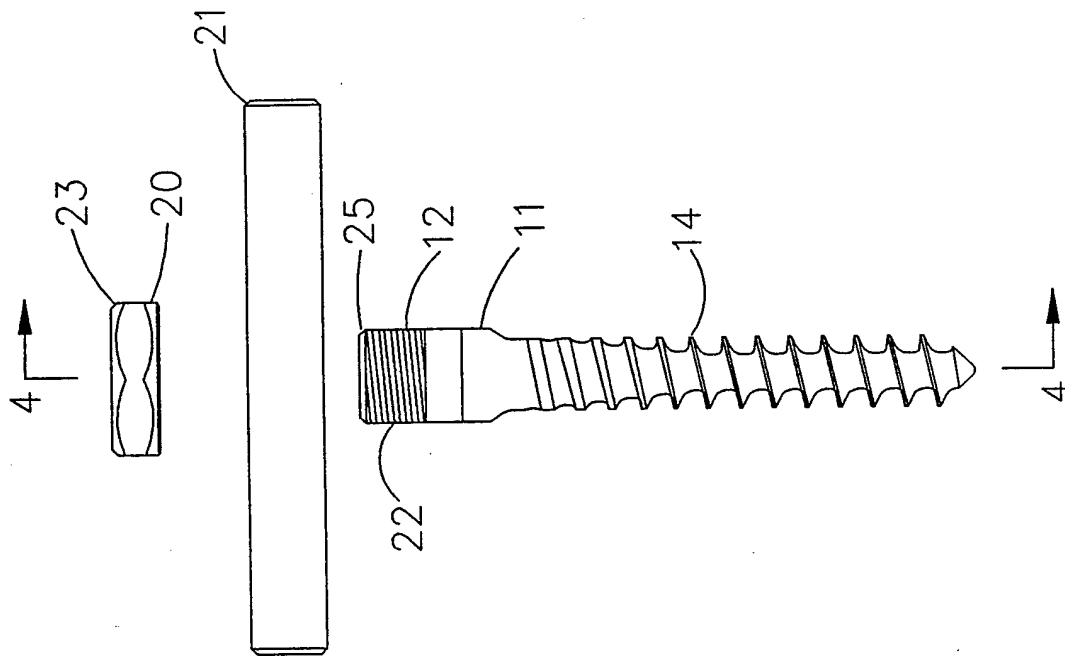


FIG. 1

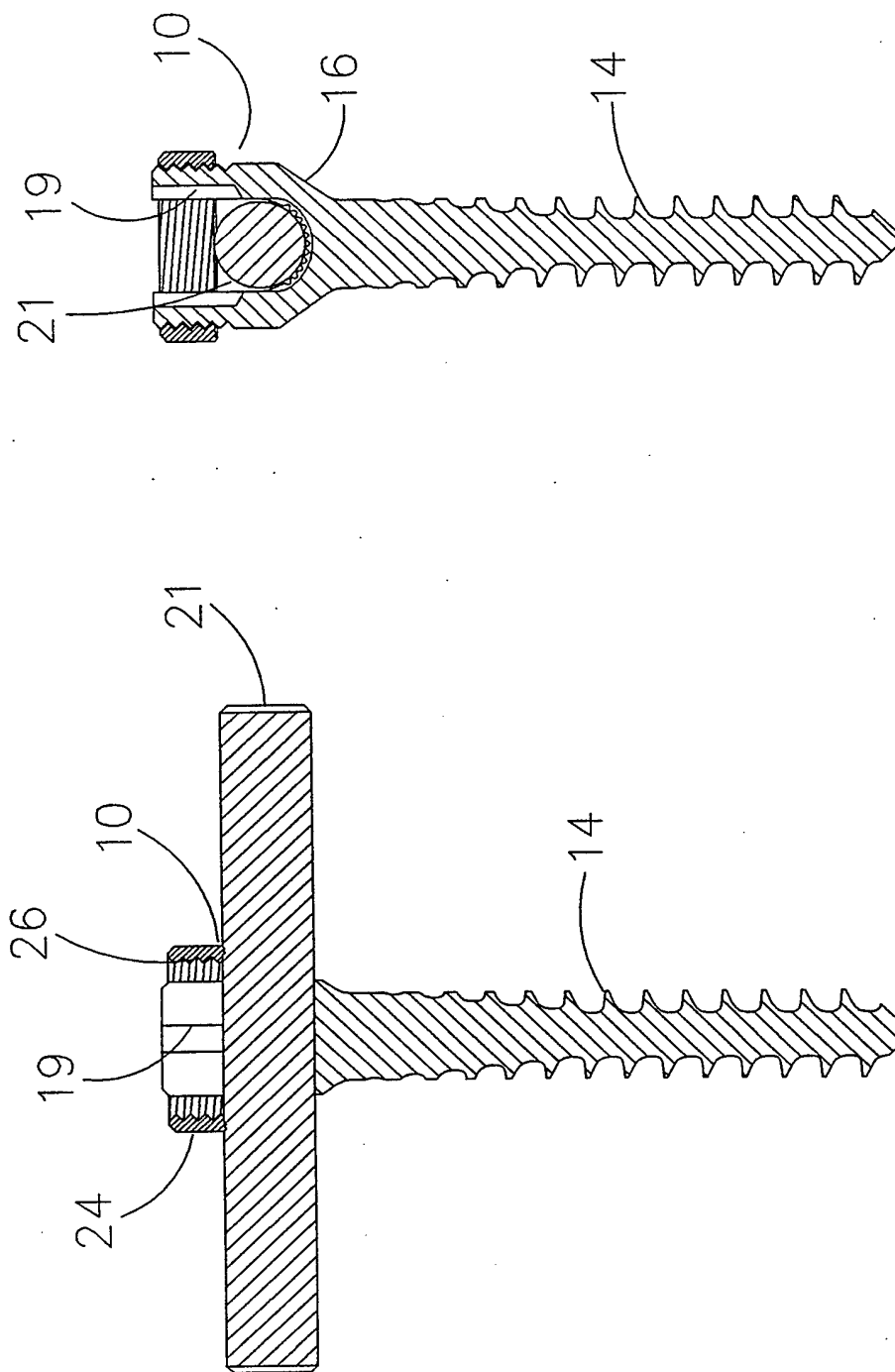


FIG. 4

FIG. 3

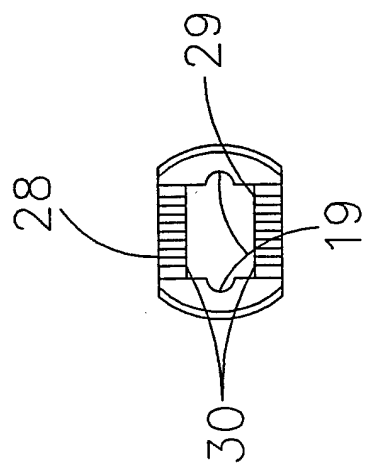
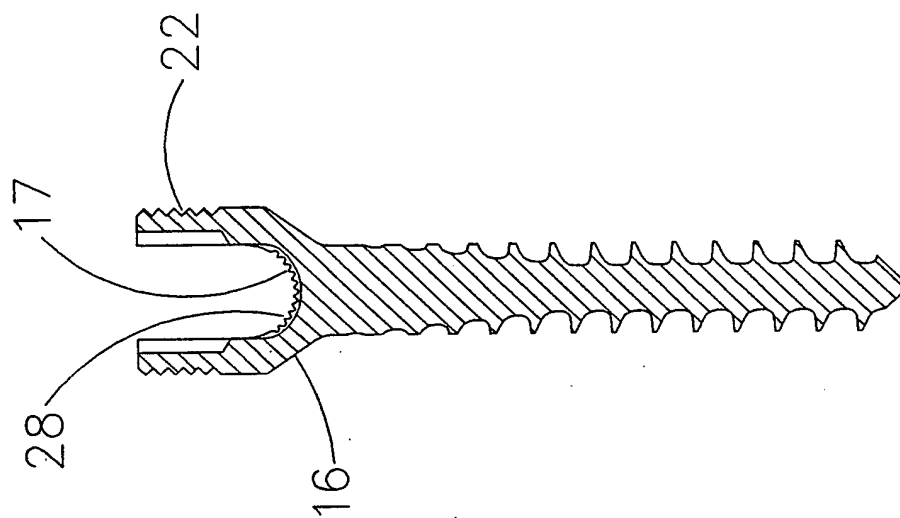


FIG. 5

FIG. 6

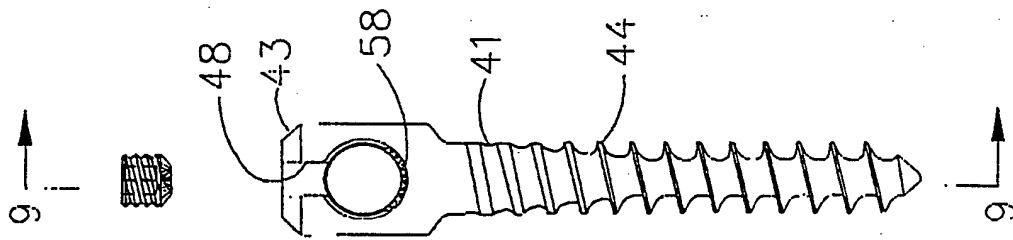


FIG. 8

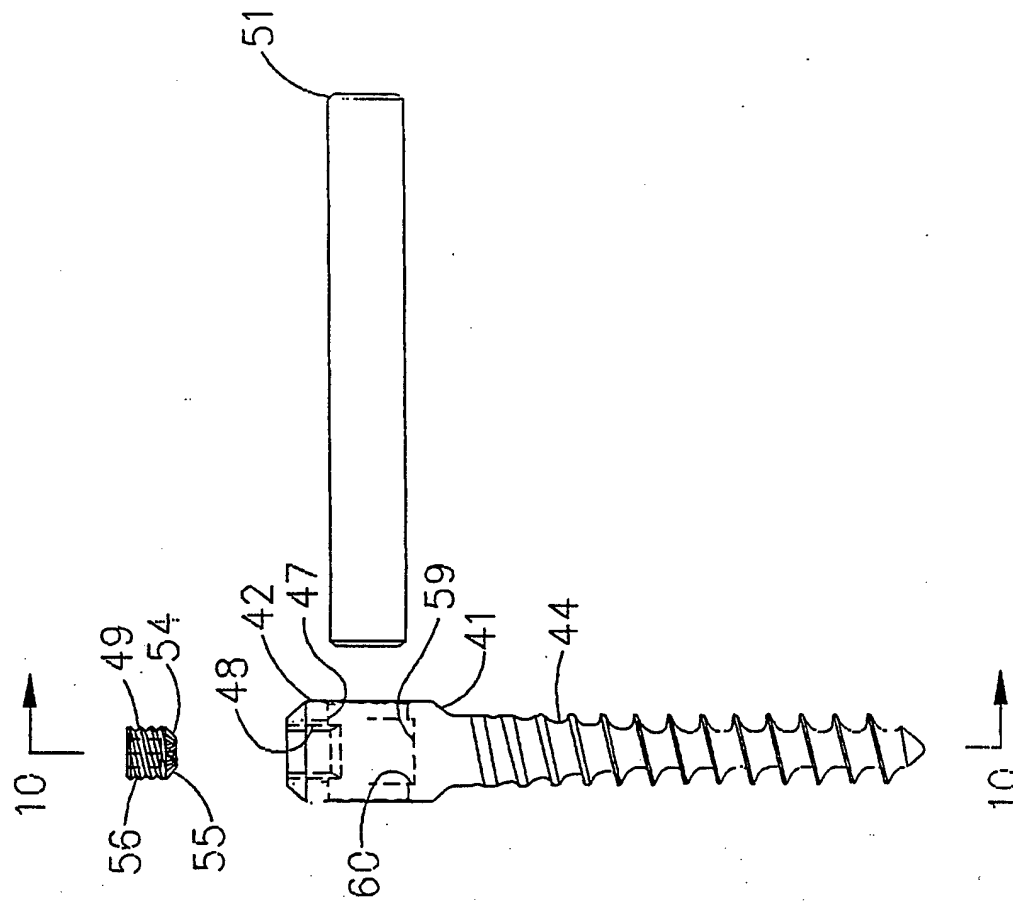


FIG. 7

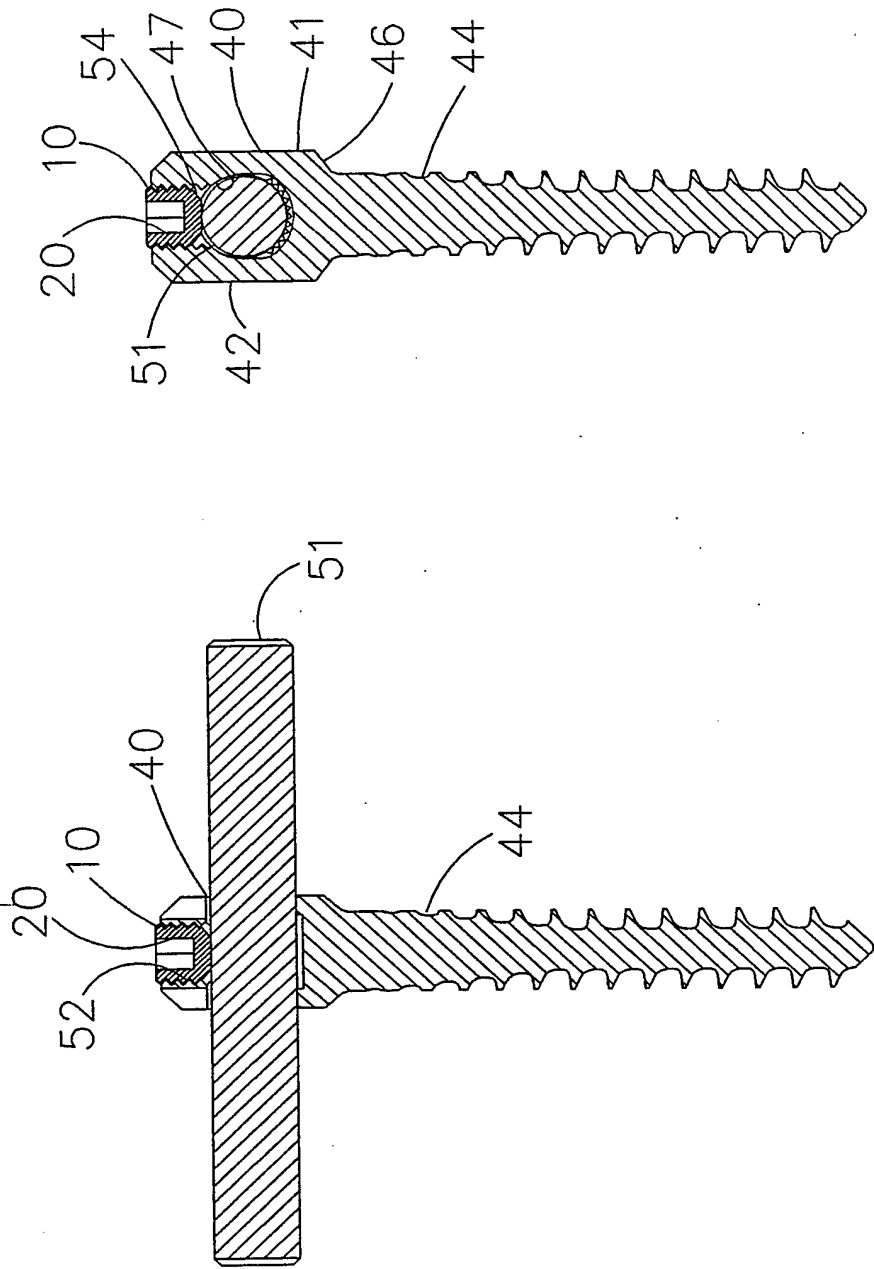


FIG. 9

FIG. 10

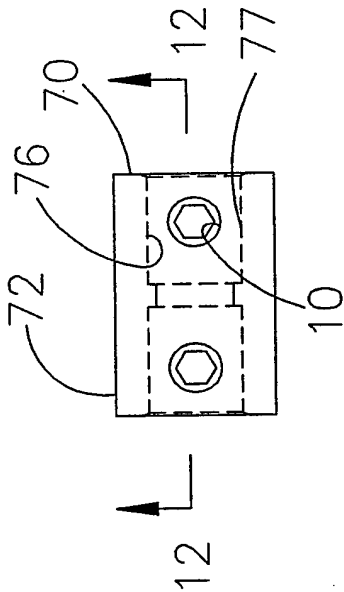


FIG. 11

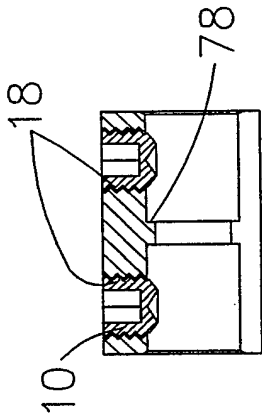


FIG. 12

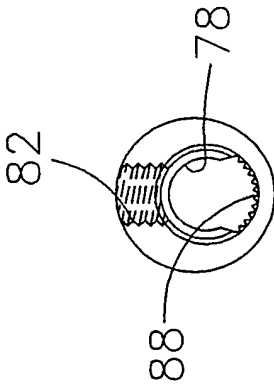


FIG. 13

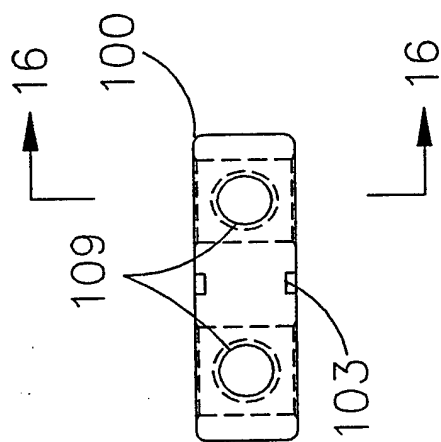


FIG. 15

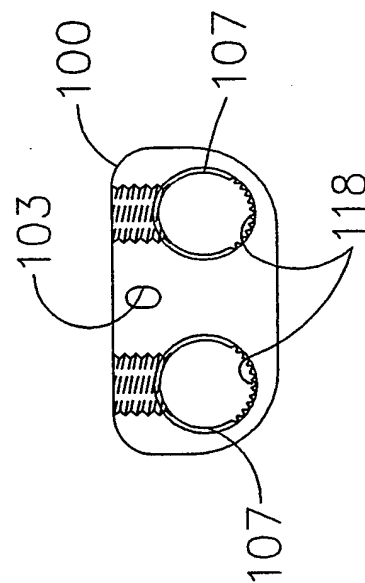


FIG. 14

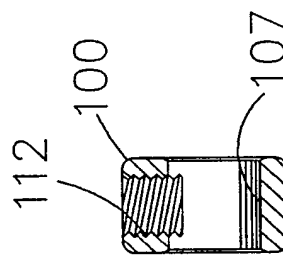


FIG. 16

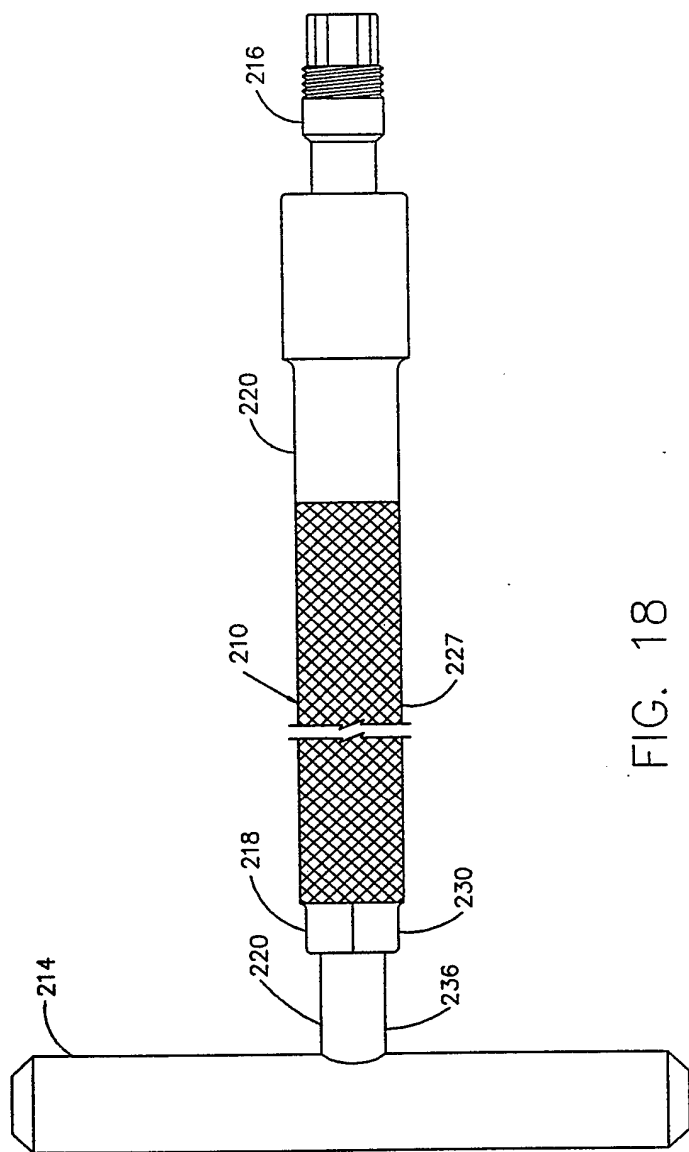


FIG. 18

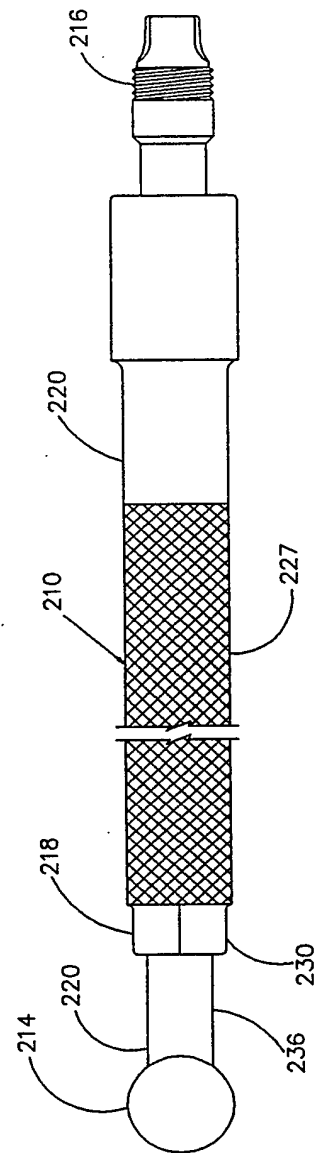


FIG. 17

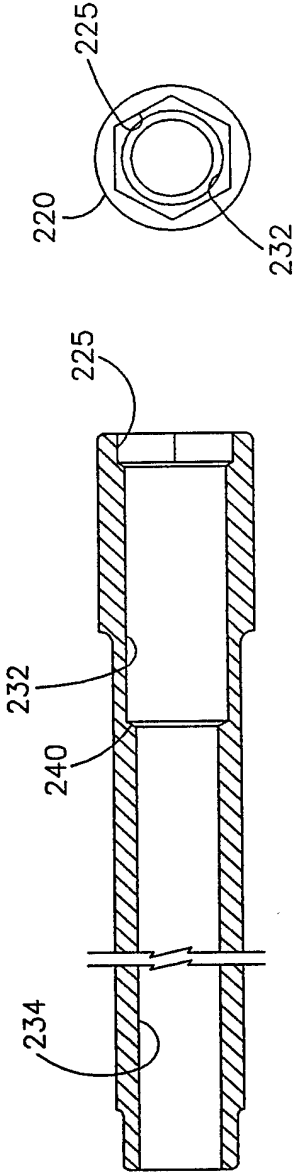


FIG. 21

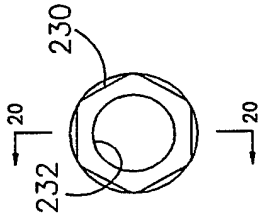


FIG. 22

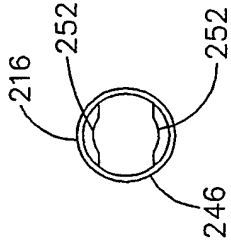


FIG. 19

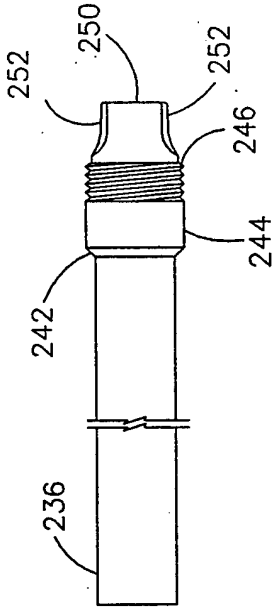


FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13318

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/70, 17/90; F16B 7/00

US CL :403/362; 606/61, 86

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 403/305, 362, 389, 391; 606/60, 61

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,257,993 (ASHER ET AL.) 02 November 1993. See entire document.	1, 8, 9 ----- 2-7, 11
X --- Y	US, A, 4,653,481 (HOWLAND ET AL.) 31 March 1987. See entire document.	8, 10 ----- 2-7, 11
X --- Y	US, A, 5,005,562 (COTREL) 09 April 1991. See entire document.	12, 13 ----- 14

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 16 FEBRUARY 1995	Date of mailing of the international search report 20 MAR 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer <i>Tamara L. Graysay</i> TAMARA L. GRAYSAY Telephone No. (703) 308-0858

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13318

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 3,191,139 (SCHIFFMANN) 22 June 1965. See Fig. 5 embodiment with longitudinal serration interrupted by transverse channel.	15-17
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Y		14
X	US, A, 780,850 (WILLIAMS) 24 January 1905.	15, 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13318

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
1-17
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-14, drawn to an anchor.

Group II, claims 15-17, drawn to a connector.

Group III, claims 18-23, drawn to a nut alignment guide.

Groups I, II and III, the inventions listed in these groups do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions contain different special technical features. For example:

Group I is an anchor for anchoring a rod to a spine;

Group II is a connector for connecting two rods together; and,

Group III is a guide tool for alignment of a compression nut.

Further, each of the inventions has separate utility.